Complete Summary

GUIDELINE TITLE

Asthma.

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. Asthma. Ann Arbor (MI): University of Michigan Health System; 2006 Feb. 16 p. [15 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: University of Michigan Health System. Asthma. Ann Arbor (MI): University of Michigan Health System; 2004 Sep. 15 p.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

On November 18, 2005, the U.S. Food and Drug Administration (FDA) notified manufacturers of Advair Diskus, Foradil Aerolizer, and Serevent Diskus to update their existing product labels with new warnings and a Medication Guide for patients to alert health care professionals and patients that these medicines may increase the chance of severe asthma episodes, and death when those episodes occur. All of these products contain long-acting beta2-adrenergic agonists (LABA). Even though LABAs decrease the frequency of asthma episodes, these medicines may make asthma episodes more severe when they occur. A Medication Guide with information about these risks will be given to patients when a prescription for a LABA is filled or refilled. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Asthma

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management

CLINICAL SPECIALTY

Allergy and Immunology
Critical Care
Emergency Medicine
Family Practice
Internal Medicine
Nursing
Pediatrics
Pharmacology
Pulmonary Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Pharmacists
Physician Assistants
Physicians
Respiratory Care Practitioners

GUIDELINE OBJECTIVE(S)

To improve the patient's quality of life by achieving and maintaining control of symptoms; attaining normal lung function; minimizing need for as-needed beta2-agonists; avoiding adverse effects from asthma medications; preventing exacerbations; attaining normal activity levels, including exercise; and preventing emergency visits and hospitalizations

TARGET POPULATION

Children, adolescents, and adults with asthma

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation/Diagnosis

1. Physical examination and patient history (to determine if symptoms and signs of asthma are present)
2. Objective measurements of airflow obstruction (spirometry)
3. Exclusion of alternative diagnoses

Management

1. Education of patients to develop a partnership in asthma management
2. Assessment of asthma severity with objective measures of lung function (peak expiratory flow rate [PEFR] monitoring)
3. Avoidance or control of asthma triggers:
    - Indoor allergens
    - Outdoor allergens
    - Food triggers
    - Indoor air pollution
    - Medications
    - Exercise
    - Concurrent medical conditions (infections [e.g., viral upper respiratory infection, bronchitis, sinusitis], allergic rhinitis, gastroesophageal reflux disease)
4. Establish medication plans for chronic management
    - Anti-inflammatory medications:
        - Inhaled corticosteroids
        - Systemic corticosteroids
        - Leukotriene receptor antagonists
        - Non-steroidal drugs with anti-inflammatory properties: cromolyn sodium and nedocromil
    - Bronchodilator medications:
        - Inhaled, short-acting beta2-agonists
        - Inhaled, long-acting beta2-agonists
        - Methylxanthines
        - Anticholinergics (Note: The benefits of daily use of anticholinergics for asthma in children and adults have not been established, even though they are commonly used for refractory patients.)
        - Recombinant anti-immunoglobulin E (anti-IGE) antibody: Omazulimab
        - Antireflux therapy for gastroesophageal reflux disease (GERD) patients with asthma
        - Use of bronchodilators: pediatric considerations and home nebulizers
5. Establish plans for managing exacerbations
6. Regular follow-up care and consultation or referral as appropriate

MAJOR OUTCOMES CONSIDERED

- Symptom relief

- Patient quality of life
- Drug interactions and side effects
- Asthma associated morbidity and mortality
- Peak expiratory flow rate (PEFR)
- Occurrence of rescue beta-agonist use

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developers identified relevant data via a Medline search that included the following terms: asthma, peak flow meter, spirometry, diagnosis, treatment, randomized controlled trials, practice guidelines. Also reviewed were literature referenced in the National Asthma Education Program's Executive summary: Guidelines for the diagnosis and management of asthma, 1994, and the international consensus report on diagnosis and treatment of asthma: A call to action for US practitioners, Clinical Therapeutics 1994;16(4):694-706.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence for the Most Significant Recommendations

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Decision analysis
D. Opinion of expert panel

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Conclusions were based on prospective randomized clinical trials if available, to the exclusion of other data; if randomized controlled trials were not available,

observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Consideration of benefits, harms, costs, and patient preferences

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

University of Michigan Health System (UMHS) guidelines are reviewed by leadership in departments to which the content is most relevant. Guidelines are approved by the Executive Committee of Clinical Affairs (ECCA). The changes in this update were reviewed by members of the following departments: Allergy; Emergency Medicine; Family Medicine; General Internal Medicine; Pediatrics & Communicable Diseases; Pharmacy; Pulmonary & Critical Care Medicine.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): The following key points summarize the content of the guideline. Refer to the full text for additional information, including detailed information on diagnosis, six-part asthma management program, dosing and cost of drugs as well as charts for predicted average peak expiratory flows.

The levels of evidence [A-D] are defined at the end of the "Major Recommendations" field.

- A high index of suspicion for asthma is essential. A history of both symptoms and symptom triggers should be obtained. [C]

- Objective evaluation of airflow obstruction is key to the diagnosis, classification, and management of the disease. Goals of treatment should include not only symptomatic relief, but normalization of lung function [C].
- Therapy should focus on long-term suppressive therapy. Anti-inflammatory agents (in particular inhaled corticosteroids) are the cornerstone of therapy for moderately and severely affected patients. Inhaled beta2-agonists should represent "rescue" agents in most instances [B].
- Patient education should emphasize how to identify and avoid environmental triggers of asthma and smoking cessation. Patients with moderate or severe asthma should be able to measure their peak expiratory flow rate (PEFR) at home and modify their therapy or seek help based on their performance relative to their personal best peak flow value. Self-management is fundamental to successful therapy [A], so a structured asthma education program should be considered.

Definitions:

Levels of Evidence for the Most Significant Recommendations

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Decision analysis
D. Opinion of expert panel

CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document for the management of asthma.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Patients with asthma gain symptomatic relief and functional benefit from several classes of anti-inflammatory and bronchodilator medications and from education in self-management of the disease.

Subgroups Most Likely to Benefit

- Patients experiencing difficulty with traditional Metered Dose Inhaler (MDI) technique
- African-Americans have asthma-related mortality rates that are higher than Caucasians' rates.

POTENTIAL HARMS

Side Effects Associated with Pharmacotherapy

Anti-inflammatory Agents

- Inhaled corticosteroids
    - There is a dose-dependent reduction of short-term growth with the use of conventional doses of beclomethasone dipropionate. Long-term linear growth does not appear to be affected by moderate doses (400-800 mcg/day) of inhaled corticosteroids, except in prepubertal males.
    - Osteopenia is a concern with inhaled corticosteroids in the adult population and increases with dose and duration of use. There also appears to be some increase in risk of cataracts with long term use of inhaled steroids.
    - High doses of inhaled corticosteroids may cause systemic side effects (though to a much lesser extent than oral steroids will).
- Systemic corticosteroids
    - Chronic systemic corticosteroid therapy may be associated with obesity, moon facies, supraclavicular and nuchal fat pads, striae, easy bruisability, weakness, hypertension, osteopenia, and glucose intolerance. Children may also exhibit growth failure. Long-term (>2 weeks) corticosteroid therapy may cause suppression of the hypothalamic-pituitary-adrenal axis. Full recovery of the axis can take up to 12 months depending on the dose, frequency, and duration of antecedent therapy. Symptoms and signs of secondary adrenal insufficiency include weakness, weight loss, and gastrointestinal discomfort. Adrenal insufficiency can evolve into acute adrenal crisis precipitated by severe infection, trauma, or surgery. Clinical presentation includes fever, dehydration, hypotension, nausea, vomiting, and hypoglycemia.
- Inhaled beta2-agonists
    - Several epidemiologic studies have found an association between excess use of beta2-agonist (short and long-acting) inhalers and asthma mortality. A causal relationship has not been demonstrated, and it is possible that beta2-agonists represent a mere marker for the severity of disease, being more frequently prescribed for patients with life-threatening asthma. If beta2-agonists do have a causative role, it may be an indirect one, such as delaying presentation until airway obstruction is more severe.
- Home nebulizers
    - Patients who regularly need to use a beta2-agonist nebulizer are unstable and need more aggressive baseline therapy.

Drug Interactions

Leukotriene modifier agents: Zafirlukast can potentiate warfarin and theophylline as well as interact with several other medications.

Subgroups Most Likely to be Harmed

Beta2-agonists: Safety and efficacy of the inhaled, long-acting beta2-agonist salmeterol has not been established in children less than 4 years of age, and for formoterol in children less than 5 years of age.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm
Patient Resources
Staff Training/Competency Material

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. Asthma. Ann Arbor (MI): University of Michigan Health System; 2006 Feb. 16 p. [15 references]

ADAPTATION

This guideline was partially adapted from:

National Heart, Lung, and Blood Institute "Expert panel report 2: guidelines for the diagnosis and management of asthma". Bethesda (MD): U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Heart, Lung and Blood Institute; 1997 Jul.

It also uses material from the 2004 update for asthma in pregnancy, NIH Publication No. 05-3279.

DATE RELEASED

1996 Dec (revised 2006 Feb)

GUIDELINE DEVELOPER(S)

University of Michigan Health System - Academic Institution

SOURCE(S) OF FUNDING

Internal funding for University of Michigan Health System (UMHS) guidelines is provided by the Office of Clinical Affairs. No external funds are used.

GUIDELINE COMMITTEE

Asthma Guideline Team

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Team Leader: Lee Green, MD MPH, Family Medicine

Team Members: James L. Baldwin, MD, Allergy; F. John Brinley, MD, General Internal Medicine; James A Freer, MD, Emergency Medicine; Cyril M. Grum, MD, Pulmonary & Critical Care Medicine; Martin E. Hurwitz, MD, Pediatrics & Communicable Diseases; Cary E. Johnson, PharmD, College of Pharmacy; Benjamin Song, MD, Pediatrics & Communicable Diseases

Guidelines Oversight Team: Connie J. Standiford, MD; William E Chavey, MD; R. Van Harrison, PhD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The University of Michigan Health System endorses the Guidelines of the Association of American Medical Colleges and the Standards of the Accreditation Council for Continuing Medical Education that the individuals who present educational activities disclose significant relationships with commercial companies whose products or services are discussed. Disclosure of a relationship is not intended to suggest bias in the information presented, but is made to provide readers with information that might be of potential importance to their evaluation of the information.

Team Member; Company; Relationship

James L Baldwin, MD (none)

F John Brinley, MD (none)

Cary E Johnson, PharmD (none)

James A Freer, MD (none)

Lee A Green, MD, MPH (none)

Cyril M Grum, MD (none)

Martin E Hurwitz, MD, Glaxo-Smith-Kline, Merck, Pfizer, Speaker's bureau; Astra-Zeneca, Glaxo-Smith-Kline, Merck, Novartis, Sub-investigator; Pfizer, Stockholder

Benjamin Song, MD, Pfizer, Consultant; Glaxo-Smith-Kline, Merck, Pfizer, Speaker's bureau

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: University of Michigan Health System. Asthma. Ann Arbor (MI): University of Michigan Health System; 2004 Sep. 15 p.

GUIDELINE AVAILABILITY

Electronic copies: Available for download in Portable Document Format (PDF) from the University of Michigan Health System Web site.

AVAILABILITY OF COMPANION DOCUMENTS

Continuing Medical Education (CME) information is available from the University of Michigan Health System Web site.

PATIENT RESOURCES

The following are available:

- Asthma. University of Michigan Health System; 2005 Jun. Various p. Electronic copies: Available from the University of Michigan Health System Web site.
- Peak flow meter: using the zone system. University of Michigan Health System; 2005 Jun. Various p. Electronic copies: Available from the University of Michigan Health System Web site.
- Peak flow meter: how to monitor asthma. University of Michigan Health System; 2005 Jun. Various p. Electronic copies: Available from the University of Michigan Health System Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on August 21, 2000. The information was verified by the guideline developer on November 22, 2000. This NGC summary was updated on November 8, 2004. The updated information was verified by the guideline developer on December 7, 2004. This summary was updated by ECRI on December 5, 2005 following the U.S. Food and Drug Administration (FDA) advisory on long-acting beta2-adrenergic agonists (LABA). This NGC summary was updated by ECRI on February 23, 2006. The updated information was verified by the guideline developer on March 17, 2006.

COPYRIGHT STATEMENT

This NGC summary is based on the original guideline, which is copyrighted by the University of Michigan Health System (UMHS).

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx.

NGC, AHRQ, and its contractor ECRI make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

© 1998-2006 National Guideline Clearinghouse

Date Modified: 9/25/2006